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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

DAVID L R

ART UNIT

PAPER NUMBER

1651
DATE MAILED:

7
10/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/856,694

Applicant(s)

SIMON ET AL.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-39 is/are pending in the application.
- 4a) Of the above claim(s) 20-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 36-39 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☒ Claim(s) 20-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 20 - 32, drawn to a composition.

Group II, claim(s) 33 - 35, drawn to a method of preparing a composition

Group III, claim(s) 36 - 39, drawn to a method for treating disease.

2. The inventions listed as Groups I, II and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In the instant application, the prior art discloses compositions containing hyperforin and or hypericin (see submitted IDS and Notice of References Cited). Therefore a special technical feature does not exist between the groups, establishing a lack of unity between the inventions.

3. During a telephone conversation with Patricia Granados on October 9, 2001 a provisional election was made without traverse to prosecute the invention of Group III, claims 36 - 39.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 20 - 35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

5. Claim 37 is objected to because of the following informalities: The term "ecezema" should be spelled "eczema". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 36 – 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36 and its dependents are drawn to a method for treating disease however are rendered vague and indefinite for reciting "geriatric skin" because it is not what this term encompasses as it is not adequately defined by the claim language or specification. Furthermore, it is not clear how "geriatric skin" is a disease.

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Claim 36 and its dependents are rendered vague and indefinite because they depend on a non-elected claim. It is not clear what composition is administered to effect the method for treating disease.

Claim 36 and its dependent are rendered vague and indefinite for reciting "precancerous conditions" because the term is not adequately defined by the claim language or specification.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 36 – 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Angeli et al. (WO 91/15218).

Applicant claims a method for treating a disease selected from cancer, inflammatory skin diseases, precancerous conditions, geriatric skin or microbial skin infections comprising topical administration of an effective amount of a composition comprising (a) hyperforin or (b) hyperforin and hypericin, in a suitable carrier, to a subject in need thereof. Specifically, the disease is eczema, exciccation eczema, hyperkeratotic hand and foot eczema, contact eczema,

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atopic dermatitis, neurodermatitis, lichen simplex, prurigo simplex, lymphoma, leukemia, melanoma, epithelial precancerous conditions, tumor metastases or epithelial tumor and the subject is a mammal.

Angeli et al. teach therapeutic compositions for treating psoriasis (an inflammatory skin disease) wherein the composition comprises an active ingredient extracted from St. John's Wort (*Hypericum perforatum*) (abstract) and a carrier suitable for topical application (p.10). In addition, it is disclosed that extracts of *H. perforatum* are used externally in treatments of skin disorders and slow-healing wounds (p.8).

Although Angeli et al. do not specifically teach the extract of St. John's Wort containing hyperforin and/or hypericin, it was known in the art that extracts of St. John's Wort contain both hyperforin and hypericin as active ingredients (see "Scientific Description of *Hypericum Perforatum*", listed on PTO 892). Furthermore, although Angeli et al. do not teach the method wherein each of the named diseases are treated, the method steps are the same. Moreover, by practicing the method of Angeli et al., one would inherently be practicing the method as claimed by applicant. Therefore, the reference anticipates the claimed subject matter.

10. Claims 36 – 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Khan (GB 2311009 A).

Applicant claims a method for treating a disease selected from cancer, inflammatory skin diseases, precancerous conditions, geriatric skin or microbial skin infections comprising topical administration of an effective amount of a composition comprising (a) hyperforin or (b) hyperforin and hypericin, in a suitable carrier, to a subject in need thereof. Specifically, the

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disease is eczema, exsiccation eczema, hyperkeratotic hand and foot eczema, contact eczema, atopic dermatitis, neurodermatitis, lichen simplex, prurigo simplex, lymphoma, leukemia, melanoma, epithelial precancerous conditions, tumor metastases or epithelial tumor and the subject is a mammal.

Khan teaches pharmaceutical compositions comprising extracts of *Hypericum perforatum* wherein the composition treats fungal infection and skin lesions (abstract). Specifically, the composition is used to treat hyperkeratosis, eczema, inflammatory conditions, viral and fungal infections (p.1) and psoriatic lesions (p.4). The composition is disclosed to contain topical carriers such as isopropyl alcohol (p.1).

Although Khan does not specifically teach the extracts containing hyperforin and/or hypericin, it was known in the art that extracts of *Hypericum perforatum* contain both hyperforin and hypericin as active ingredients (see "Scientific Description of *Hypericum Perforatum*", listed on PTO 892). Furthermore, although Khan does not teach the method wherein each of the named diseases are treated, the method steps are the same. Moreover, by practicing the method of Khan, one would inherently be practicing the method claimed by applicant. Therefore, the reference anticipates the claimed subject matter.

11. Claims 36 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Shatkina et al. (US 4911925).

Applicant claims a method for treating a disease selected from cancer, inflammatory skin diseases, precancerous conditions, geriatric skin or microbial skin infections comprising topical administration of an effective amount of a composition comprising (a) hyperforin or (b)

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hyperforin and hypericin, in a suitable carrier, to a subject in need thereof wherein the subject is a mammal.

Shatkina et al. teach a topical cream that prevents or delays the aging, deterioration and wrinkling of skin (geriatric skin) (col.1 line 10-15) containing a vegetable extract of *Hypericum perforatum* (col.2 line 20-25). The vegetable extract is disclosed to possess highly bactericidal, antiseptic and anti-inflammatory properties (col.3 line 5-11).

Although Shatkina et al. do not specifically teach the extracts containing hyperforin and/or hypericin, it was known in the art that extracts of *Hypericum perforatum* contain both hyperforin and hypericin as active ingredients (see "Scientific Description of *Hypericum Perforatum*", listed on PTO 892). Moreover, by practicing the method of Shatkin et al, one would inherently be practicing the method claimed by applicant. Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 36 – 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khan (GB 2311009 A), Shatkina et al. (US 4911925), Khwaja et al. (WO 97/39355), Valavichyus et al. (1986) and The Hypericum Home Page (<http://www.hypericum.com/hyp20.htm>).

Applicant claims a method for treating a disease selected from cancer, inflammatory skin diseases, precancerous conditions, geriatric skin or microbial skin infections comprising topical administration of an effective amount of a composition comprising (a) hyperforin or (b) hyperforin and hypericin, in a suitable carrier, to a subject in need thereof. Specifically, the disease is eczema, exsiccation eczema, hyperkeratotic hand and foot eczema, contact eczema, atopic dermatitis, neurodermatitis, lichen simplex, prurigo simplex, lymphoma, leukemia, melanoma, epithelial precancerous conditions, tumor metastases or epithelial tumor and the subject is a mammal.

Khan teaches pharmaceutical compositions comprising extracts of *Hypericum perforatum* wherein the composition treats fungal infection and skin lesions (abstract). Specifically, the composition is used to treat hyperkeratosis, eczema, inflammatory conditions, viral and fungal infections (p.1) and psoriatic lesions (p.4). The composition is disclosed to contain topical carriers such as isopropyl alcohol (p.1).

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Shatkina et al. (US 4911925) teach a topical cream that prevents or delays the aging, deterioration and wrinkling of skin (geriatric skin) (col.1 line 10-15) containing a vegetable extracts of Hypericum perforatum (col.2 line 20-25). The vegetable extract is disclosed to possess highly bactericidal, antiseptic and anti-inflammatory properties (col.3 line 5-11).

Although Khan and Shatkina et al. do not specifically teach the extracts containing hyperforin and/or hypericin, it was known in the art that extracts of Hypericum perforatum contain both hyperforin and hypericin as active ingredients (see "Scientific Description of Hypericum Perforatum", listed on PTO 892). Furthermore, although the references do not teach the methods wherein each of the named diseases are treated, the method steps are the same. Moreover, by practicing the methods of Khan and/or Shatkina et al., one would inherently be practicing the method claimed by applicant.

The above references do not teach administering the compositions for treating cancer, precancerous conditions or tumors. However, at the time the invention was made, one of ordinary skill in the art would have been motivated to do so because The Hypericum Home Page (1996) teaches extracts of Hypericum perforatum (St. John's Wort), specifically hypericin, demonstrates anticancer properties and has been proven to inhibit tumor cells of the brain, lung and skin (p.4). In addition, Khwaja et al. teach clinical indications of St. John's Wort extracts include antibacterial, anticancer, antimutagenic and antiviral uses (p.86). Finally, Valavichyus et al. teach that extracts of St. John's Wort, specifically oil extracts, inhibits growth of sarcoma cells (abstract). At the time the invention was made, one of ordinary skill in the art would have been motivated to utilize the methods and compositions of Khan and/or Shatkina et al. to treat

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cancer and/or tumors with a reasonable expectation of success because of the known action against tumor and cancer cells as demonstrated by the references cited above.


The above references do not teach the methods for treating each of the named skin disorders as claimed by applicant. However, at the time the invention was made, one of ordinary skill in the art would have been motivated to do so because the extracts containing hyperforin and/or hypericin were each well known in the art to be effective treatments against various skin diseases, inflammation disorders and infections as demonstrated by the references cited above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis
October 15, 2001



LEON B. LANKFORD, JR.
PRIMARY EXAMINER